

**Notice of Allowability**

Application No.

10/664,995

Examiner

Carl H. Layno

Applicant(s)

SEIFERT ET AL.

Art Unit

3766

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Papers filed July 21, 2006.
2. ☒ The allowed claim(s) is/are 1-16.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☒ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 5. <input type="checkbox"/> Notice of Informal Patent Application                     |
| 2. <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)            | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input type="checkbox"/> Examiner's Amendment/Comment                              |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance             |
|  | 9. <input type="checkbox"/> Other _____   |

### **DETAILED ACTION**

1. Acknowledgment is made of applicant's amendment, which was received by the Office on July 21, 2006.

2. Claims 1-16 are active and pending.

#### ***Specification***

3. In view of the applicant's modifications to the specification, the Examiner is withdrawing the objections, which were made against the specification in the last Office action.

#### ***Claim Rejections - 35 USC § 102***

4. Upon further reconsideration of applicant's arguments and Examiner's Amendments (below) to the claims, the Examiner is withdrawing the 35 U.S.C 102(e) rejection of Swoyer et al (US 6,754,536), which was made against claims 1, 9, and 10 in the last Office action.

#### ***Claim Rejections - 35 USC § 103***

5. Upon further reconsideration of applicant's arguments and the Examiner's amendments to the claims (below), the Examiner is withdrawing the 35 U.S.C 103(a) rejection of Swoyer et al (US 6,754,536) in view of Spehr (US 5,851,227), which was made against claims 3, 5, 15, and 16 in the last Office action.

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*Examiner's Amendment*

6. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Carol F. Barry on September 27, 2006.

The application has been amended as follows:

-Please re-write claim 1 as follows:

"1. A medical electrical lead, comprising:  
a hollow needle,  
a flexible lead body within the hollow needle including a distal end, a first elongated insulated conductor extending toward the distal end and a first electrode coupled to the first conductor;  
a second elongated insulated conductor including a first portion extending within the lead body to the distal end and a second portion extending distally from the distal end of the lead body;  
a tissue anchor terminating the second portion of the second conductor and including a surface for receiving a push force from an insertion tool adapted to deploy the anchor from within said hollow needle to engage a segment of tissue such that the first electrode of the lead body is in close proximity to the segment of tissue; and  
a second electrode mounted on the tissue anchor and coupled to the second conductor."

-Please re-write claim 9 as follows:

"9. A medical electrical lead, comprising:  
a hollow needle,  
a flexible lead body within the hollow needle including a distal end, a first elongated insulated conductor extending toward the distal end and a first electrode coupled to the first conductor;  
a second elongated insulated conductor including a first portion extending within the lead body to the distal end and a second portion extending distally from the distal end of the lead body;

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a tissue anchor terminating the second portion of the second conductor and including a means for receiving a push force from an insertion tool adapted to deploy the anchor from within said hollow needle to engage a segment of tissue such that the first electrode of the lead body is in close proximity to the segment of tissue; and  
a second electrode mounted on the tissue anchor and coupled to the second conductor.”

-Please re-write claim 10 as follows:

“10. A medical electrical lead, comprising:  
a hollow needle,  
a flexible lead body within the hollow needle including a distal end, a first elongated insulated conductor extending toward the distal end and a first electrode coupled to the first conductor;  
a second elongated insulated conductor including a first portion extending within the lead body to the distal end and a second portion extending distally from the distal end of the lead body;  
a tissue anchor terminating the second portion of the second conductor;  
a second electrode mounted on the tissue anchor and coupled to the second conductor; and  
an insertion tool adapted to push the anchor out of the hollow needle and into a segment of tissue in order to implant the first electrode in proximity to the tissue and the second electrode within the segment of tissue;  
wherein the anchor includes a surface receiving the push from the insertion tool.”

*Allowable Subject Matter*

7. Claims 1-16 are allowed.

*Conclusion*

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

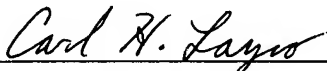
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The Curry (US 4,497,326) patent is cited for its pertinent lead structure (Fig.1). Unlike applicant's device, Curry does not specify the use of a "hollow needle" for initially containing the flexible lead body..

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on 9/4/5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



CARL LAYNO  
PRIMARY EXAMINER

CHL  
9/27/2006